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REMARKS

In a teleconference with Examiner Ungar on April 20, 2004, it was agreed that the Examiner would call the undersigned prior to issuing an Office Action in the above-identified application.

Rejection under 35 USC §101

4. Attached is the executed declaration by Dr. Zairen Sun. This declaration was provided earlier, although it had not been signed. This declaration provides additional evidence using RT-PCR technology that the claimed polynucleotides are up-regulated in breast cancer tissues when compared to normal breast tissues. See, e.g., Paragraph No. 5 of Dr. Sun's declaration.

Rejection under 35 USC §112

5-6. On Page 4 of the Office action, the examiner continues to allege that claim 3 and others are not in conformance with §112, first paragraph.

The claim specifically recites the following about the claimed polynucleotide (and the polypeptide it encodes): "97% or more nucleotide sequence identity", "having 614 amino acids", "has transcriptional regulatory activity", and "is up-regulated in a human breast cancer." The specification coupled with a skilled worker's knowledge provides adequate guidance to make and use the invention without undue experimentation, e.g., to determine polynucleotides within the scope of the claim. "To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

The first paragraph of 35 U.S.C. §112 effectively requires that "the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art." *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970). To determine whether there is a reasonable correlation between the scope of the claims and the

scope of enablement, the degree of predictability of the relevant art may need to be considered. See, *Plant Genetic Systems, N.V. and Biogen, Inc. v. Dekalb Genetics Corporation*, 315 F.3d 1335 (Fed. Cir. 2003).

The present application provides a polynucleotide sequence, methods of nucleic acid detection (e.g., beginning on Page 15, line 12), and methods of measuring transcriptional activity (e.g., Page 3, lines 10-25). Methods of hybridization can be used to detect sequences which hybridize under high stringency conditions to the sequence set forth in SEQ ID NO:1. In view of this disclosure and the mature state of the art, it is evident that the skilled worker at the time the application was filed could routinely determine other polynucleotides which fall within the scope of the claims. It would be completely predictable that such polynucleotides (e.g., polymorphisms, etc.) could be isolated using conventional techniques.

According to the M.P.E.P 2164.04: "In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." The examiner has not identified a single specific, substantial, or credible reason as to why the scope of enablement is exceeded, and has therefore failed to meet the burden of setting forth the enablement rejection.

Moreover, Applicant has amended the claims to recite specific hybridization conditions. Support for this amendment can be found in specification, e.g., Page 10, lines 1-5. This claim type has been determined by the Patent Office to meet the requirements of §112, first paragraph.

See, Example 9 of the *Written Description Guidelines.*

As far as the rejections relating to the phrase "complement thereto," Applicant has amended the claims in the manner suggested by the examiner. Such amendment does not change the scope of the claims since the skilled worker would have reasonably construed the original term ("complement") in the claims to have the same scope as the substituted phrase ("complete complement").

Nonetheless, a search of the of the PTO patent database revealed 2340 DNA patents which used the term "complement thereto" in the claims, and only 32 patents which recited the examiner's preference "complete complement thereto." See, Exhibit 1. Many of these patents refer to a sequence identification number ("SEQ ID NO"), and then to the **complement** of it. It is not logical that the claimed complement would be broader the sequence associated with its identifier, and therefore, it is evident that the term "complement" as utilized in over 98% of the patents in Exhibit 2 is understood to mean "complete complement," making the amendment unnecessary.

7. It has been conceded by the examiner that SEQ ID NO:1 has an adequate written description (Page 6: "although the Written Description of SEQ ID NO:1 is clear"). However, the examiner has taken the position that no fragment of this described SEQ ID NO:1 has a written description. This includes fragments:

(1) coding for amino acids 1-263 of SEQ ID NO:2 (claim 6);

(2) coding for amino acids 459-614 of SEQ ID NO:2 (claim 6)

(3) for a polypeptide comprising at least eight amino acids in length (claim 8)

(4) specific for human Urb-ctf and comprising certain amino acid positions recited in SEQ ID NO:2 (claim 5)

(5) having the characteristics of (4) and which are also effective as a primer in a polymerase chain reaction (claim 7)

These claims are in conformance with the written description requirement. First, all of these claims are original claims and are described in the specification as filed. Therefore, they necessarily have a written description. Secondly, the Court of Customs and Patent Appeals (predecessor to the Federal Circuit) has held that a broad range provides adequate written description of a narrower range. In *In re Wertheim*, 191 USPQ 90 (CCPA 1973), the Applicant for a patent had described a broad range of 25% to 60% solids in a Swiss patent application. A claim was added during the U.S. filing to a range "between 35% and 60%." The Patent Office rejected this claim as lacking a written description. On appeal, the court reversed the Patent Office's decision, holding that the skilled worker would have considered processes employing a 35-60% range to be part of the Applicant's invention.

Analogously, the skilled worker would have recognized that any fragment of the described SEQ IS NO: 1 (or NO:2) is part of Applicant's invention. The examiner has not provided any specific explanation as to why Applicant does not have possession of fragments (1)-(5) summarized above, nor has the examiner distinguished between the various fragment types.

10. Claim 3 has been amended to recite that the "full-length human Urb-ctf" is "having 614 amino acids." This would have been understood from reading the specification, since the latter protein was described as having such length.

Rejection under 35 U.S.C. §102

8. The claims have been amended to recite the "complete complement thereof." Therefore, it is believed that this rejection is now moot. This amendment, as stated above (Paragraph No. 5-6), does not change the claim scope in any way.

9. Claims 5 and 7 remain rejected under Section 102(b) as allegedly anticipated by Konno et al.

It was stated in the Office action that "Applicant has chosen not to submit said evidence" to prove the claimed product is different from that allegedly taught by the prior art.

This was not the intended case. The information to make such distinction was in the application as originally filed. Kono et al. refers to GenBank entry AL049450. See Office action dated July 30, 2003, Page 27. The latter GenBank entry is specifically referenced in the Specification on Page 2, line 30 and compared to the SEQ ID NO:2 in Fig. 1 as filed. AL049450 is also known as XM_058887. Fig. 1 clearly shows the differences between the two sequences at the claimed positions.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: ORIGEN-0015

Date: April 20, 2004

In re Application of: SUN et al.

Serial No.: 10/054,935 Examiner: Susan Ungar, Ph.D

Filed: January 25, 2002 Group Art Unit: 1642

For: **BREAST CANCER TRANSCRIPTION FACTOR GENE AND USES**

Declaration Under 37 C.F.R. §1.132

1. I, Zairen Sun, Ph.D., am an inventor of the subject matter described and claimed in the above-identified U.S. Patent Application which is assigned to OriGene Technologies. I am also Director of Research and Development of OriGene Technologies, Inc

2. The following experiments were performed by me, or under my supervision.

3. Polyadenylated mRNA was isolated from normal breast and breast cancer tissue samples, and used as a template for first-strand cDNA synthesis. Samples were obtained from 12 different breast cancers, and 12 different normal breasts. The resulting cDNA samples were normalized using beta-actin as a standard. For the normalization procedure, PCR was performed on aliquots of the first-strand cDNA using beta-actin specific primers. The PCR products were visualized on an ethidium bromide stained agarose gel to estimate the quantity of beta-actin cDNA present in each sample. Based on these estimates, each sample was diluted with buffer until each contained the same quantity of beta-actin cDNA per unit volume.

4. To detect gene expression, PCR was carried out on aliquots of the normalized tissue samples using oligonucleotide primers specific for BCU1041: ATTCTTGATGCCCCTATCTCAAGAGGAA (forward primer), and GAACATGGCAGGTGAGTAAAAGTTGACC (reverse primer). The reaction products were loaded on to an agarose (e.g., 1.5-2%) gel and separated electrophoretically. The lane at the far left of each panel contains molecular weight standards. See, attached Fig. 1.

5. As shown in attached Fig. 1, significant up-regulation of BCU1041 was observed in at least 8 of the 12 different tissue samples from breast cancers. The arrow indicates the expected position of the amplified segment of BCU1041 mRNA. In contrast, this product was absent in the normal breast cancer tissues.

6. I declare further that all statements made in this Declaration are of my own knowledge and are true and that all statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

4/16/2004

Date

Zairen Sun

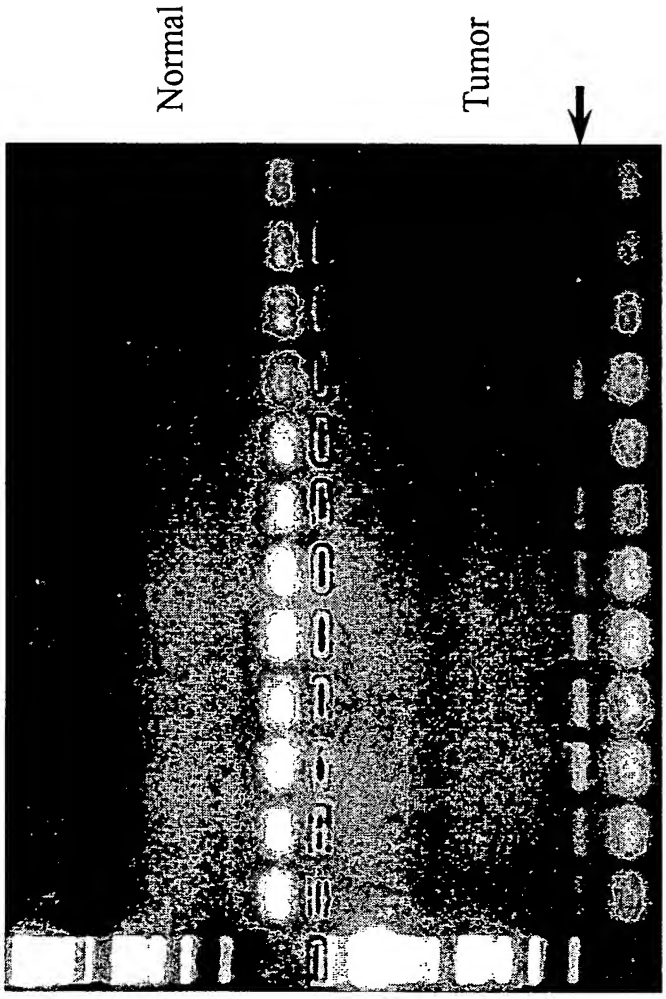

Fig. 1

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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ACLM/"complement thereto" AND DNA: 2340 patents.
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Refine Search ACLM/"complement thereto" AND DNA

	PAT. NO.	Title
1	6,720,477	Signal transduction stress-related proteins and methods of use in plants
2	6,720,476	CTR1 homologue from melon
3	6,720,181	Ubiquitin ligases as therapeutic targets
4	6,720,172	Genes encoding sulfate assimilation proteins
5	6,720,166	Non-a, non-b, non-c, non-c, non-d, non-e hepatitis reagents and methods for their use
6	6,720,146	Compositions and methods for the therapy and diagnosis of ovarian cancer
7	6,716,625	Histidine kinases of Aspergillus and other fungal species, related compositions, and methods of use
8	6,716,616	Human kinase proteins and polynucleotides encoding the same
9	6,716,607	Chicken interferon gene and novel recombinant DNA
10	6,716,604	Nucleic acid molecules encoding a subunit of a human calcium/calmodulin-dependent protein kinase
11	6,716,576	Method of assaying Neutrokine-.alpha. mRNA level
12	6,716,575	Diagnosis and treatment of AUR1 and/or AUR2 related disorders
13	6,716,432	Pneumolysin mutants and pneumococcal vaccines made therefrom
14	RE38,490	Method for identifying metastatic sequences
15	6,713,666	Invertase inhibitors and methods of use
16	6,713,606	Conjugates of soluble peptidic compounds with membrane-binding agents
17	6,713,259	Corn event MON810 and compositions and methods for detection thereof
18	6,713,066	Production of attenuated respiratory syncytial virus vaccines involving modification of M2 ORF2

19 6,710,229 Cell cycle stress-related proteins and methods of use in plants
20 6,710,170 Compositions and methods for the therapy and diagnosis of ovarian cancer
21 6,710,027 Bacillus thuringiensis toxins and genes for controlling coleopteran pests
22 6,709,863 Nucleic acid molecules encoding multiple start codons and histidine tags
23 6,709,842 DNA encoding a growth factor specific for epithelial cells
24 6,709,838 Nucleic acid encoding patched-2
25 6,709,829 Methods and compositions for detection of disease
26 6,709,816 Identification of alleles
27 6,709,812 Method for typing and detecting HBV
28 6,706,948 Sugarcane UBI9 gene promoter and methods of use thereof
29 6,706,509 Oncoprotein protein kinase
30 6,706,491 Reagents and methods for identifying and modulating expression of genes regulated by p21
31 6,706,485 Method of identifying agents that inhibit APP processing activity
32 6,706,472 Group of nucleic acid molecules salmonella detection, nucleic acids, kit and use
33 6,706,262 Compounds and methods for therapy and diagnosis of lung cancer
34 6,703,495 Polynucleotides encoding human transporter protein
35 6,703,491 Drosophila sequences
36 6,703,489 Antibodies to vertebrate serrate proteins and fragments
37 6,703,229 Aryl propenal double bond reductase
38 6,703,221 Notch receptor ligands and uses thereof
39 6,703,220 Human neurogenin 3-encoding nucleotide sequences
40 6,699,980 Nucleic acid molecule encoding a mismatch endonuclease and methods of use thereof
41 6,699,704 Heat tolerant phytases
42 6,699,703 Nucleic acid and amino acid sequences relating to Streptococcus pneumoniae for diagnostics and therapeutics
43 6,699,664 Compositions and methods for the therapy and diagnosis of ovarian cancer
44 6,699,663 Molecular sequence of swine retrovirus
45 6,699,476 Production of recombinant respiratory syncytial viruses expressing immune modulatory molecules
46 6,696,619 Plant aminoacyl-tRNA synthetases
47 6,696,561 Corynebacterium glutamicum genes encoding proteins involved in membrane synthesis and membrane transport
48 6,696,293 Process for producing carotenoids and biological materials useful therefor
49 6,696,292 Genes encoding sulfate assimilation proteins
50 6,696,256 Method, array and kit for detecting activated transcription factors by hybridization array

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Results of Search in 1976 to present db for:
ACLM/"complete complement thereto" AND DNA: 32 patents.
Hits 1 through 32 out of 32

Jump To

Refine Search ACLM/"complete complement thereto" AND DNA

	PAT. NO.	Title
1	6,720,146	Compositions and methods for the therapy and diagnosis of ovarian cancer
2	6,699,980	Nucleic acid molecule encoding a mismatch endonuclease and methods of use thereof
3	6,686,188	Polynucleotide encoding a human myosin-like polypeptide expressed predominantly in heart and muscle
4	6,686,185	25934, a novel fatty acid desaturase and uses therefor
5	6,682,888	Genes expressed in alzheimer's disease
6	6,680,191	Isolated nucleic acid molecules coding for tumor rejection antigen precursors of members of the MAGE-C and MAGE-B FAMILIES and uses thereof
7	6,656,700	Isoforms of human pregnancy-associated protein-E
8	6,632,934	MORC gene compositions and methods of use
9	6,623,937	Programmed cell death antagonist protein
10	6,620,922	Compositions and methods for the therapy and diagnosis of prostate cancer
11	6,590,089	RVP-1 variant differentially expressed in Crohn's disease
12	6,569,657	32140, a novel human aldehyde dehydrogenase and uses therefor
13	6,541,236	Protein having glutaminase activity and gene encoding the same
14	6,531,280	Method for identifying or isolating a molecule and molecules identified thereby
15	6,518,411	RGS compositions and therapeutic and diagnostic uses therefor
16	6,509,155	Nucleic acids encoding GTPase activating proteins
17	6,503,700	Mammalian CDP-diacylglycerol synthase
18	6,500,942	Rin2, a novel inhibitor of Ras-mediated signaling
19	6,500,642	Molecule associated with apoptosis
20	6,479,263	Method for detection of micrometastatic prostate cancer
21	6,476,212	Polynucleotides and polypeptides derived from corn ear

22 6,455,292 Full-length serine protein kinase in brain and pancreas
23 6,448,041 Colon cancer marker
24 6,444,456 Human G-coupled protein receptor kinases and polynucleotides encoding the same
25 6,436,687 cDNA sequence of mouse brain sialidase gene
26 6,355,430 Diagnostic and screening methods employing KIAA0101
27 6,355,245 C5-specific antibodies for the treatment of inflammatory diseases
28 6,344,549 ATR-2 cell cycle checkpoint
29 6,274,720 Human preproneurotensin/neuromedin N
30 6,265,556 Nucleic acid encoding CD40 associated proteins
31 6,168,933 Phospholipid transfer protein
32 6,124,436 Purified mammalian monocyte antigens and related reagents

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